

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 1:24mj03189 Goodman

UNITED STATES OF AMERICA

v.

ADAM BROSIUS,

Defendant.

FILED BY ER D.C.

Jun 14, 2024

ANGELA E. NOBLE
CLERK U.S. DIST. CT.
S. D. OF FLA. - Miami

CRIMINAL COVER SHEET

1. Did this matter originate from a matter pending in the Northern Region of the United States Attorney's Office prior to August 8, 2014 (Mag. Judge Shaniek M. Maynard)? No
2. Did this matter originate from a matter pending in the Central Region of the United States Attorney's Office prior to October 3, 2019 (Mag. Judge Jared M. Strauss)? No
3. Did this matter involve the participation of or consultation with now Magistrate Judge Eduardo I. Sanchez during his tenure at the U.S. Attorney's Office, which concluded on January 22, 2023? No
4. Did this matter involve the participation of or consultation now Magistrate Judge Marty Fulgueira Elfenbein during her tenure at the U.S. Attorney's Office, which concluded on March 5, 2024? No

Respectfully submitted,

MARKENZY LAPOINTE
UNITED STATES ATTORNEY

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UNITED STATES DISTRICT COURT
for the
Southern District of Florida

United States of America)
v.)
ADAM BROSNIUS,) Case No. 1:24mj03189 Goodman
)
)
)
)

Defendant.

CRIMINAL COMPLAINT BY TELEPHONE OR OTHER RELIABLE ELECTRONIC MEANS

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of April 2020 to August 2021 in the county of Miami-Dade in the
Southern District of Florida, the defendant(s) violated:

Code Section

18 U.S.C. § 371

Offense Description

Conspiracy to introduce into interstate commerce adulterated and
misbranded drugs

This criminal complaint is based on these facts:

SEE ATTACHED AFFIDAVIT.

Continued on the attached sheet.



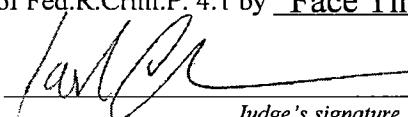
Complainant's signature

Carlos Baixauli Jr. - Special Agent, HHS-OIG

Printed name and title

Attested to by the Applicant in accordance with the requirements of Fed.R.Crim.P. 4.1 by Face Time

Date: 6/14/24



Judge's signature

City and state: Miami, Florida

Honorable Jonathan Goodman, United States Magistrate Judge
Printed name and title

AFFIDAVIT

I, Special Agent Carlos Baixauli Jr., being duly sworn, do hereby depose and state:

Introduction

1. I am a Special Agent with the United States Department of Health and Human Services, Office of Inspector General (“HHS-OIG”), currently assigned to the Miami Regional Office. I have been a Special Agent since 2019. Prior to that, I worked for the Coral Gables Police Department for eight years, and I also worked for five years in several financial intelligence units at several major financial institutions.

2. In this capacity, I am authorized to conduct investigations into and make arrests for various federal criminal offenses, including, but not limited to, health care fraud, prescription drug diversion, drug misbranding, money laundering, and related conspiracies. I have received training in investigating various types of criminal activity, including fraud, at the Federal Law Enforcement Training Center in Brunswick, Georgia, and the HHS-OIG training center in Largo, Maryland.

3. I make this affidavit in support of a criminal complaint charging Adam Brosius (“BROSIUS”) with conspiracy to commit an offense against the United States, that is, with the intent to defraud and mislead, to introduce and deliver for introduction into interstate commerce, and cause to be introduced and delivered for introduction into interstate commerce, adulterated and misbranded drugs, in violation of Title 18, United States Code, Section 371, and Title 21, United States Code, Sections 331(a) and 333(a)(2). The facts contained in this affidavit are based on my personal knowledge and observations as well as facts relayed to me by other law enforcement officers, witnesses, and documents. Based on my training and experience and the facts set forth in this affidavit, there is probable cause to believe that **BROSIUS** committed the crime described above.

4. This affidavit does not contain all the facts of this investigation known to me or to other law enforcement personnel. Rather, it sets forth only those facts necessary to establish probable cause in support of a criminal complaint charging **BROSIUS** with conspiracy to commit an offense against the United States, that is, with the intent to defraud and mislead, to introduce and deliver for introduction into interstate commerce, and cause to be introduced and delivered for introduction into interstate commerce, adulterated and misbranded drugs, in violation of Title 18, United States Code, Section 371, and Title 21, United States Code, Sections 331(a) and 333(a)(2).

The Defendant and Related Entities and Individual

5. Safe Chain Solutions LLC (“Safe Chain”) was a limited liability company organized under the laws of the State of Delaware with offices in Cambridge, Maryland, and Miami, Florida. Safe Chain was a wholesale distributor that purported to sell legitimate prescription drugs, including expensive human immunodeficiency virus (“HIV”) drugs, to pharmacies located throughout the United States.

6. Worldwide Pharma Sales Group, Inc. (“Worldwide Pharma Sales”), also known as WW Pharma Sales, was a corporation organized under the laws of the State of Delaware with a business address of 455 NE 5th Ave., Suite D434, Delray Beach, Florida. Worldwide Pharma Sales helped Safe Chain locate both suppliers of HIV drugs and pharmacy customers to purchase HIV drugs.

7. Drug Manufacturer 1 was a biopharmaceutical company that manufactured, among other things, HIV drugs.

8. Boulevard 9229, LLC (“Boulevard”) was a limited liability company organized under the laws of the State of New York with a business address of 9229 Queens Boulevard, Suite 11, Rego Park, New York.

9. Gentek LLC (“Gentek”) was a limited liability company organized under the laws of the State of Connecticut with a business address of 45 Cedar Street, Unit 3, Stamford, Connecticut.

10. Defendant **BROSIUS**, a resident of Palm Beach County, Florida, was the owner of Worldwide Pharma Sales and an owner of Safe Chain.¹

11. Co-Conspirator 1 was a sales broker who worked with **BROSIUS** and others to buy and sell HIV drugs through Safe Chain. Co-Conspirator 1 has pleaded guilty to one count of conspiracy to introduce into interstate commerce misbranded drugs and to defraud the United States, in violation of Title 18, United States Code, Section 371, and Title 21, United States Code, Sections 331(a) and 333(a)(2), and one count of introducing into interstate commerce a misbranded drugs, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2). Co-Conspirator 1 is cooperating with the government in the hope of receiving a more lenient sentence.

Regulatory Background

12. The U.S. Food and Drug Administration (“FDA”) was the federal agency responsible for protecting the health and safety of the American public by, among other things, regulating the distribution and sale of prescription drugs and enforcing the Federal Food, Drug, and Cosmetic Act (“FDCA”), Title 21, United States Code, Sections 301 *et seq.* One of the purposes of the FDCA was to ensure that drugs sold for use by humans were safe, effective, and bore labeling containing only true and accurate information.

¹ On or about July 10, 2020, **BROSIUS** was indicted in the United States District Court for the District of New Jersey on health care fraud and kickback charges arising from a compounding pharmacy fraud scheme. *See United States v. Andrews et al.*, 20-CR-587 (D.N.J. 2020). **BROSIUS** is awaiting trial in that case.

13. Federal law, including Title 21, United States Code, Section 360eee-1, generally required that prescription drugs sold in the United States by or to wholesale distributors be accompanied by product tracing information, which consisted of transaction information, transaction history, and a transaction statement. The product tracing information identified, among other things, the product, the quantity, the lot number, strength and dosage, the date of each sale, and the parties to each transaction. Such product tracing information was commonly referred to in the industry as “T3s” or “pedigrees.”

14. Under the FDCA, “drugs” were defined as, among other things, articles intended for use in the cure, mitigation, treatment, or prevention of disease, pursuant to Title 21, United States Code, Section 321(g)(1)(B). A “prescription drug” was any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, or was limited by an approved application under Title 21, United States Code, Section 355 to use under the professional supervision of a practitioner licensed by law to administer such drug, pursuant to Title 21, United States Code, Section 353(b)(1).

15. The introduction or delivery for introduction, or the causing thereof, into interstate commerce of any drug that was adulterated or misbranded was a violation of federal law, pursuant to Title 21, United States Code, Section 331(a).

16. A drug was adulterated if, among other things, any substance had been substituted in whole or in part for the drug, pursuant to Title 21, United States Code, Section 351(d).

17. A drug was misbranded if, among other things, its labeling was false or misleading in any particular, pursuant to Title 21, United States Code, Section 352(a)(1). A “label” was written, printed, or graphic matter upon the immediate container of the drug, while “labeling” was

a broader term that included all labels and other written, printed, or graphic matter upon the drug or any of its containers or wrappers, or that accompanied the drug, pursuant to Title 21, United States Code, Section 321(k) and (m).

Prescription Drug Diversion

18. The term “prescription drug diversion” referred to the various ways in which prescription drugs were removed from regulated distribution channels and subsequently reintroduced into the wholesale marketplace. Common methods of prescription drug diversion included, but were not limited to, acquiring the drugs illegally through fraud or from individual patients for whom the prescription drugs had been prescribed and dispensed but intentionally not consumed. These diverted drugs were then reintroduced into the marketplace with false documentation concealing their true source and eventually resold to individual consumers by pharmacies, which also typically billed the drugs to “health care benefit programs,” as defined by Title 18, United States Code, Section 24(b). Once diverted from the regulated distribution channel, it became difficult for regulators and consumers to know whether a prescription drug was altered, stored in improper conditions, had its potency adversely affected, or was otherwise harmful.

Probable Cause

19. As part of the investigation, I personally interviewed witnesses and reviewed documentary evidence, including, but not limited to, financial records, emails and other electronic messages, and text messages. This evidence shows that **BROSIUS**, Co-Conspirator 1, and their co-conspirators, through Safe Chain and Worldwide Pharma Sales, began buying diverted HIV drugs from Boulevard in or around May 2020. Also, in or around May and June 2020, **BROSIUS**, Co-Conspirator 1, and their co-conspirators began reselling the diverted HIV drugs sourced from Boulevard to pharmacies located throughout the United States, including to pharmacies in the Southern District of Florida. According to financial records for Safe Chain, between in or around

May 2020 and in or around March 2021, **BROSIUS** and his co-conspirators bought diverted HIV drugs from Boulevard and resold those drugs to pharmacies.

20. According to financial records for Safe Chain, beginning in or around June 2020, **BROSIUS**, Co-Conspirator 1, and their co-conspirators began buying diverted HIV drugs from Gentek and reselling those diverted drugs to pharmacies located throughout the United States. According to Co-Conspirator 1, s/he located Gentek as a supplier of HIV drugs and served as a middleman broker between **BROSIUS** and Safe Chain, on the one hand, and Gentek. According to financial records, between in or around June 2020 and in or around January 2021, **BROSIUS**, Co-Conspirator 1, and their co-conspirators bought diverted HIV drugs from Gentek and resold those drugs to pharmacies.

21. Evidence that the HIV drugs **BROSIUS**, Co-Conspirator 1, and their co-conspirators acquired from Boulevard and Gentek and resold to pharmacies were adulterated, misbranded, and diverted includes, but is not limited to: (1) the discounted pricing of the HIV drugs; (2) the physical appearance of the bottles of HIV drugs; (3) instances in which the bottles of HIV drugs they bought and resold contained the wrong drug inside; and (4) the falsified T3s/pedigrees that they received, created, and provided to pharmacies accompanying their sales of the HIV drugs.

22. The heavily discounted pricing of the HIV drugs involved in the conspiracy is a strong indicator that the drugs **BROSIUS**, Co-Conspirator 1, and their co-conspirators bought and resold were not obtained through the legitimate channels of distribution.

23. Based on my training and experience and review of evidence in this case, I know that Drug Manufacturer 1 manufactures Biktarvy and other prescription HIV drugs. I also know that Drug Manufacturer 1 sells Biktarvy and other HIV drugs only at the Wholesale Acquisition

Cost (“WAC”). As a result, according to representatives of Drug Manufacturer 1, its products are not available at steep discounts below the WAC sales price. Nevertheless, evidence reviewed by law enforcement – including sales records and communications among **BROSIUS** and others – confirmed that **BROSIUS**, Co-Conspirator 1, and their co-conspirators purchased Biktarvy and other HIV drugs at steep discounts – typically between 15% to 25% below WAC – over the course of approximately 14 months. **BROSIUS**, Co-Conspirator 1, and their co-conspirators then resold those heavily discounted HIV drugs to pharmacies located throughout the United States.

24. Based on my training and experience, review of documents, and interviews of witnesses, I know that evidence that drugs are adulterated and/or misbranded can be found by looking at the physical appearance of the bottles, what labeling is or is not attached to them, and the drugs’ packaging. I reviewed evidence of Safe Chain pharmacy customers’ complaints about the HIV drugs the pharmacies purchased from Safe Chain. For example, I reviewed an October 3, 2020, email in which a pharmacy customer of Safe Chain sent an email to **BROSIUS** and his co-conspirators complaining about the HIV drugs it purchased from Safe Chain, and attaching the following photo of the drugs in question:



The pharmacy customer wrote in the email: "The items were quarantined immediately after we discovered a suspicious packaging . . . The inventory is not usable for us, since it is deemed as not meeting safety standards and may present risk for our patients." Based on my training and experience, the bottles of drugs in above photo show obvious signs of misbranding and diversion because the bottles appear worn, suggesting they had previously been dispensed, and some do not even appear to have the directions for use attached to them. I know that the directions for use for HIV drugs are typically attached to the bottles and contain important information for patients who consume the drugs. Despite receiving this pharmacy complaint concerning the drugs **BROSIUS** and his co-conspirators acquired from Boulevard, **BROSIUS** and his co-conspirators continued reselling misbranded HIV drugs obtained from Boulevard to pharmacies for another approximate six months.

25. Additionally, I reviewed email correspondence sent to **BROSIUS** confirming that the T3s/pedigrees Boulevard provided to Safe Chain, and which Safe Chain used to create its own

T3s/pedigrees, were falsified. For example, I reviewed a September 29, 2020, email that was forwarded to **BROSIUS** by a co-conspirator at Safe Chain. In the email that was forwarded to **BROSIUS** by his co-conspirator, Safe Chain's compliance manager stated s/he was having difficulty verifying a Boulevard T3/pedigree as accurate. In addition, above the forwarded email, the co-conspirator wrote to **BROSIUS** as follows: "We've had two bad returns with opened bottles and broken pills last two days and the below sounds pretty bad." The following day, Safe Chain's compliance manager confirmed that a Boulevard T3/pedigree was falsified, based on an email from the wholesale distributor identified as selling the HIV drugs to Boulevard on the T3/pedigree confirming that the transactions on the T3/pedigree did not take place. Despite this, **BROSIUS** and his co-conspirators continued buying misbranded and diverted HIV drugs from Boulevard, while knowing that Boulevard's T3s/pedigrees were falsified, and reselling those misbranded and diverted HIV drugs, along with the falsified T3s/pedigrees, to pharmacies located throughout the United States. **BROSIUS** and his co-conspirators' sales of these misbranded HIV drugs took place until in or around March 2021, long after the emails described above.

26. Additionally, I reviewed evidence that patients complained about the bottles of medication they received from pharmacies that purchased the HIV drugs from Safe Chain. These patients complained that they received bottles that were supposed to contain their prescribed HIV drugs but which actually contained different drugs inside the bottles. **BROSIUS**, Co-Conspirator 1, and their co-conspirators were made aware of these complaints, with at least one as early as August 2020, but continued buying and reselling adulterated, misbranded, and diverted HIV drugs from the same suppliers for many months after the complaints. For instance, law enforcement interviewed a patient who, in or around February 2021, received a bottle labeled as containing Biktarvy and noticed that the pills looked different from what s/he usually received. This patient

nevertheless took the pill because it came from his/her trusted pharmacy. This patient also provided a photo of what the pills s/he normally received looked like (left), next to the bottle of pills s/he received that were supplied by Safe Chain (right):



After taking the adulterated, misbranded, and diverted drug supplied by Safe Chain, the patient suffered an adverse reaction, passing out and remaining unconscious for approximately 24 hours. The patient also reported that, based on an internet search, the shape, color, and markings of the pills in the bottle from Safe Chain labeled Biktarvy were consistent with an anti-psychotic medication.

27. I also reviewed deposition testimony of **BROSIUS** from a civil lawsuit wherein he testified that he had heard about a few instances where product sourced from Boulevard had the wrong pills inside the bottles.

28. Based on my training and experience, and review of evidence in this case, I know that diverted HIV drugs are often accompanied by falsified product tracing information, also known as T3s/pedigrees, in order to conceal the drugs' true origin. This concealment of the drugs'

true origin allows individuals, such as **BROSIUS** and his co-conspirators, to sell the drugs to pharmacies and evade detection by the FDA and law enforcement.

29. I reviewed email correspondence showing that **BROSIUS** and his co-conspirators were informed that, in order to comply with legal requirements, the drugs purchased and sold by Safe Chain had to be accompanied by a T3/pedigree pursuant to the Drug Supply Chain Security Act. A July 10, 2020, email from Safe Chain's compliance manager to **BROSIUS** and a co-conspirator stated that, “[i]n order for us to continue to purchase HIV medication from Boulevard 9229, we will need them to comply with the Drug Supply Chain Security Act. They are required to provide us information about where the drugs came from as is clearly stated in section 25 of the act.” This email also included information about the potential criminal penalties for violating Title 21, United States Code, Section 333, and included the following statement by Safe Chain's compliance manager: “It is imperative that Boulevard provide the T3 information for us, as we do not want to be put at risk should we fail to provide accurate information to our customers.”

30. In addition, a representative of Drug Manufacturer 1 reviewed the T3s/pedigrees Safe Chain created for its purchases and sales of HIV drugs from Boulevard. Based on his/her review, that representative confirmed that the T3s/pedigrees Safe Chain created and subsequently distributed along with its sales of HIV drugs sourced from Boulevard were falsified. Similarly, this representative of Drug Manufacturer 1 reviewed the T3s/pedigrees Safe Chain created for its purchases and sales of HIV drugs from Gentek. Based on his/her review, that representative confirmed that the T3s/pedigrees Safe Chain created and subsequently distributed along with its sales of HIV drugs sourced from Gentek were falsified.

31. Sales records, communications reviewed by law enforcement, and witnesses interviewed by law enforcement show that, despite being made aware that the HIV drugs

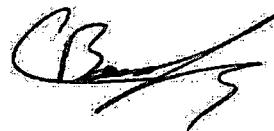
BROSIUS and his co-conspirators purchased from Boulevard and Gentek were adulterated, misbranded, and diverted, **BROSIUS** and his co-conspirators continued buying those HIV drugs from Boulevard and Gentek and reselling the adulterated, misbranded, and diverted HIV drugs to pharmacies throughout the United States. **BROSIUS** and his co-conspirators also distributed these adulterated, misbranded, and diverted HIV drugs to pharmacies while knowing that the T3s/pedigrees they provided accompanying the sales of the drugs were falsified.

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Conclusion

Wherefore, based upon the above facts, there is probable cause to believe that, from in or around at least as early as April 2020, and continuing through in or around August 2021, in Miami-Dade County, in the Southern District of Florida, and elsewhere, **BROSIUS** conspired with Co-Conspirator 1 and others to commit an offense against the United States, that is, with the intent to defraud and mislead, to introduce and deliver for introduction into interstate commerce, and cause to be introduced and delivered for introduction into interstate commerce, adulterated and misbranded drugs, in violation of Title 18, United States Code, Section 371, and Title 21, United States Code, Sections 331(a) and 333(a)(2).

FURTHER AFFIANT SAYETH NAUGHT.



CARLOS BAIXAULI JR.
SPECIAL AGENT
HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Attested to by the applicant in accordance with the requirements of Fed.R.Crim.P. 4.1
by Face Time this 14 day of June 2024.



HONORABLE JONATHAN GOODMAN
UNITED STATES MAGISTRATE JUDGE